REMARKS

I. Status of the Claims

Claims 1-19 are pending in the application. Claims 1-3, 5-7, 9-11, 16 and 17 stand rejected under 35 U.S.C. §112, first paragraph (written description), second paragraph (indefiniteness), and for alleged obviousness-type double-patenting. The specific grounds for rejection, and applicants' response thereto, are set out in greater detail below.

II. Obviousness-Type Double-Patenting

Claims 1-3, 5, 6 and 7 are rejected under the judicially-created doctrine of obviousness-type double-patenting over claims 1-4 of U.S. Patent 5,843,884, which are shown below:

> 1. A composition comprising molecules specifically modulating binding of CD59 to C9 selected from the group of molecules consisting of peptides of between 26 and 30 amino acids which bind to CD59 and molecules binding to C9 amino acid residues 359 to 384 (amino acid residues 381-406 of SEQ ID NO: 5).
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> 2. The composition of claim 1 comprising molecules selected from the group of molecules consisting of peptides of between 26 and 30 amino acids comprising hu C9 amino acid residues 359 to 384 (amino acid residues 381-406 of SEQ ID NO: 5), anti-idiotypic antibodies immunoreactive with C9 amino acid residues 359 to 384 (amino acid residues 381-406 of SEQ ID NO: 5), and covalently cyclized peptides comprising hu C9 amino acid residues 359 to 384 (amino acid residues 381-406 of SEQ ID NO: 5).
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> 3. The composition of claim 2 wherein the molecules are a peptide including amino acid residues 359 to 384 of hu C9 (amino acid residues 381-406 of SEQ ID NO: 5).
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> 4. The composition of claim 1 further comprising a pharmaceutically acceptable carrier for administration to patients in need thereof.

Applicants traverse the rejection.

In order for obviousness-type double-patenting to be proper, the claims of the instant application must be obvious over the claims of the cited patent. Here, the claims of the instant

patent are directed to a particular type of inhibitor – a peptidomimetic that corresponds to the structure of human CD59 amino acid residues 42-58. The claims of the '884 patent are directed, in a relevant aspect, to "molecules binding to C9 amino acid residues 359 to 384." Assuming that residues 42-58 of CD59 fit within this description, they would constitute a ***species*** of the genus of molecules binding to C9 amino acid residues 359 to 384. Given that nothing in the claims of the '884 patent points to the particular species of peptidomimetics of CD59 residues 42-58, the claims of the '884 are insufficient to render the present claims obvious.

Reconsideration and withdrawal of the rejection, based on the foregoing, is respectfully requested.

III. Rejection Under 35 U.S.C. §112

A. Written Description

Claims 1, 2, 7, 10, 11, 16 and 17 stand rejected under the first paragraph of §112 as lacking an adequate written description. According to the examiner, the specification fails to provide functional characteristics coupled with a known or disclosed correlation between function and structure as it reads on nucleic acids and small molecules as "peptidomimetics." Applicants traverse.

As explained in the attached declaration, with regard to mimetics generally, the specification provides specific instruction as to the structure that defines such compounds. The specification clearly indicates that the structure of human CD59 amino acid residues 42-58 of SEQ ID NO:3 must be faithfully reproduced by the mimetic. Thus, applicants were in possession of a wide variety of mimetic compounds – nucleic acids, peptides, or small molecules – that could satisfy this structural requirement.

Furthermore, attached declaration also explains that the specification provides detailed discussion of how one goes about obtaining mimetics. For example, in one aspect, the specification instructs the skilled artisan to create or obtain libraries of artificial compounds produced by combinatorial chemistry and to select from those libraries those compounds that bind to regions of interest using both competitive and non-competitive formats (see pages 17-18 of the specification). This was a matter of routine at the time the instant application was filed.

In other embodiments, a rational design is proposed, where compounds are modeled to retain the structural features of human CD59 amino acid residues 42-58 of SEQ ID NO:3 (see pages 18-24 of the specification). Detailed information on the application of computer modeling, and the synthetic generation of compounds, was provided. Either of these approaches can readily provide a plethora of compounds – nucleic acids, small molecules or peptides – that satisfy the recited structural requirements.

Thus, applicants respectfully submit that the specification adequately demonstrates possession by the inventors of a large genus of mimetics at the time of filing, including those of nucleic acid and small molecule nature. As such, applicants further submit that the written description requirement of §112 is satisfied. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. Indefiniteness

Claim 9 is rejected as indefinite under the second paragraph of §112 for alleged lack of antecedent basis. Applicants traverse. Claim 9 depends from claim 8, and claim 8 presents the term "spatial orientation." Moreover, even though properly first introduced into claim 8, the term "spatial orientation" is inherent in claim 1 in that SEQ ID NO:3 has residues with side chains, and

these side chains have spatial orientation. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

IV. Request for Interview

If for some reason this response is ***not*** deemed to place the application into condition for allowance, applicants hereby respectfully request a telephonic interview with the examiner.

V. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. Should the examiner have any questions regarding this response, a telephone call to undersigned is invited.

Respectfully submitted,

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Date: November 30, 2005